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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,269	01/14/2004	George M. Halow	A-8051.CIP.RNFMP/bh	2686
7590	10/06/2008		EXAMINER	
Jean A. Buttmi, Esq. HOFFMAN, WASSON & GITLER, PC Crystal Center 2, Suite 522 2461 South Clark Street Arlington, VA 22202			CHOI, FRANK I	
			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			10/06/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/756,269	HALOW, GEORGE M.
	<b>Examiner</b>	<b>Art Unit</b>
	FRANK I. CHOI	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 December 2007.

2a) This action is **FINAL**.                                   2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-9, 13-41 and 54-66 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-9, 13-41 and 54-66 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 14 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/2008 has been entered.

### ***Drawings***

The drawings (1/14/2004) are objected to because the views of the colon are not clearly legible due to the shading and defects caused by photocopying. Pictures must be legible when reproduced. See 37 CFR 1.84 (b)(1). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The amendment filed 9/15/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Daltons was not disclosed in the original Specification (see paragraph 0014 and claims; there is no basis in the original specification for the amendment to paragraph 0007 that disodium phosphate initiates the flow of diarrhea and that polyethylene glycol maintains the flow of diarrhea (the phrases "to initiated the flow of diarrhea" and "to maintain the flow of diarrhea" are not underlined although said phrases were not in the original Specification at pg 3 and the amendment switches the phosphate from maintaining to initiating and PEG from initiating to maintaining), to paragraph 0009 that all patients who ingested the composition reported no bloating or nausea nor any complaints of taste (in the the examples, there were patients who did complain as to taste and with respect to one of the patients there was no report at all as whether bloating or nausea occurred), to paragraph 0010 that reason for lack of osmotic imbalance is the relatively low volume and relatively fast action of the method and that it is not necessary to use electrolytes with the PEG/sodium phosphate solution to prevent an osmotic imbalance, the amendment to paragraphs 0012 and 0013 that sodium phosphate stimulates and/or intitates short-term hyper-motility which casuse fecal matter to move through the bowels and that PEG maintains this hyper-motility which assures a clean bowel for examination, the amendment to paragraph 0016 that the combined amounts first stimulate hypermotility and then maintain this hypermotility, the amendment to paragraph 0022 that not electrolytes need to be added to correct an osmotic imbalance and that the purpose of the clear liquid diet is to hydrate the patient so as to not obscure pathological features present in the colon during examination, the amendment to paragraph 0023 that flavoring or coloring agents

can be added to the dissolved sodium and PEG powders to improve palatability; there is no basis for the amendment in paragraph 0030 that the purpose for the colonoscopy was used to look for a possible cause of the diarrhea as there could have been other reasons for the colonoscopy; there is no basis in the specification as originally filed for the amendment to the abstract that the sodium phosphate powder stimulates short-term hypermotility of the intestines and that PEG maintains this hypermotility or that no osmotic imbalance necessitating the administration of electrolytes is induced.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim 67 is objected to because of the following informalities: line 4, “polyethelene” should be “polyethylene”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 67 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Since claim 67 refers to hypermotility, osmotic imbalance, initiating and maintaining diarrhea by use of the phosphate powder and PEG, respectively and Daltons, new matter is raised for reasons indicated above with respect to the Specification. Further, the specification as originally filed did not indicate that additional electrolytes were used in invention or related art to initiate

diarrhea. As such, there is no support for the negative limitation as to excluding any additional electrolytes which initiate the flow of diarrhea.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 indicates that the human is instructed to add an optional adjuvant. This creates an indefiniteness as if the adjuvant is optional why would the human be instructed to add the adjuvant to the mixture. The examiner suggests that the instruction be optional instead of the adjuvant.

### ***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
October 9, 2008

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616